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UNITED STATES DEPARTMENT OF COMMERCE  
Patent and Trademark Office  
ASSISTANT SECRETARY AND COMMISSIONER  
OF PATENTS AND TRADEMARKS  
Washington, D.C. 20231

#11

Ronald L. Wilson, Director  
Health Assessment Policy Staff  
Office of Health Affairs (HFY-20)  
Food and Drug Administration  
5600 Fishers Lane, Room 15-22  
Rockville, MD 20857

Re: DIFFERIN Solution, 0.1%

FDA Docket No. 96E- (App. 4)

Dear Mr. Wilson:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 5,212,303, which issued May 18, 1993. The application was filed on July 26, 1996, under 35 U.S.C. § 156.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A). For clarity, it would be helpful if a single Federal Register Notice is printed for all of the patents which rely upon the regulatory review period of DIFFERIN Solution, 0.1%.

Telephone inquiries regarding this matter should be directed to the undersigned at (703)306-3159.

Karin Tyson  
Legal Advisor  
Special Program Law Office  
Office of the Deputy Assistant Commissioner  
for Patent Policy and Projects

cc: Norman H. Stepno  
Burns, Doane, Swecker & Mathis, L.L.P.  
P.O. Box 1404  
Alexandria, VA 22313-1404

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Ronald L. Wilson, Director  
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Food and Drug Administration  
5600 Fishers Lane, Room 15-22  
Rockville, MD 20857

Re: DIFFERIN Gel, 0.1% #11

FDA Docket No. 96E- (App. 4)

Dear Mr. Wilson:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 5,212,303, which issued May 18, 1993. The application was filed on July 26, 1996, under 35 U.S.C. § 156.

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Telephone inquiries regarding this matter should be directed to the undersigned at (703)306-3159.

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